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HEW/RHU  
November 6, 2001



PATENT APPLICATION  
Attorney's Docket No.: 1855.1017-000 (LKS95-10)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Paul D. Ponath, Douglas J. Ringler, S. Tarran Jones, Walter Newman,  
Jose Saldanha and Mary M. Bendig

Application No.: 08/700,737 Group: 1644

Filed: August 15, 1996 Examiner: P. Gambel

For: HUMANIZED IMMUNOGLOBULIN REACTIVE WITH  $\alpha 4\beta 7$  INTEGRIN

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231	
on <u>11.12.01</u>	<u>Danielle D. Bath</u>
Date	Signature
<u>Danielle D. Bath</u>	
Typed or printed name of person signing certificate	

DECLARATION OF ROBERT B. COLVIN, M.D. UNDER 37 C.F.R. § 1.132

Assistant Commissioner for Patents  
Washington, D.C. 20231

I, Robert B. Colvin, M.D., of 31 Lancaster Street, Cambridge, Massachusetts, 02140,  
hereby declare and state that:

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1. I am Chief of the Department of Pathology at Massachusetts General Hospital and the Benjamin Castleman Professor of Pathology at Harvard Medical School, and I conduct research into the rejection of transplanted organs.
2. Dr. Andrew I. Lazarovits joined my laboratory as a research fellow in October 1982, and worked in my laboratory for about 14 months. The Act-1 hybridoma cell line was produced by Dr. Lazarovits while he was working in my laboratory.
3. Dr. Lazarovits left my laboratory to become the Director of Renal Transplantation at University Hospital, London, Ontario, Canada, and directed a research laboratory at University Hospital. Dr. Lazarovits took a sample of the Act-1 hybridoma cell line to his laboratory at University Hospital in order to continue his research using the Act-1 antibody.
4. Dr. Lazarovits died in January 1999.
5. Dr. Lazarovits and I each had possession of the Act-1 hybridoma cell line and controlled the distribution of the Act-1 hybridoma cell line in our possession from the time he left my laboratory until his death.
6. In 1992, the Act-1 hybridoma cell line was provided to Becton Dickinson Advanced Cellular Biology ("Becton Dickinson") for evaluation of the Act-1 antibody as a potential diagnostic agent. The hybridoma cell line was provided to Becton Dickinson under a Materials Transfer Agreement between The General Hospital Corporation, a not-for-profit corporation doing business as Massachusetts General Hospital, and Becton Dickinson. The Materials Transfer Agreement specified that the Act-1 hybridoma cell line, its progeny, mutants and materials derived therefrom were the property of The

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General Hospital Corporation and that the Act-1 hybridoma cell line, its progeny, mutants and materials derived therefrom were not to be transferred, distributed or released to third parties by Becton Dickinson without written consent. No such written consent was requested.

7. Becton Dickinson conducted their evaluation of the Act-1 antibody, concluded that the Act-1 hybridoma cell line and antibody did not suit their commercial purposes, and returned the Act-1 hybridoma cell line to The General Hospital Corporation.
  8. In 1995, The General Hospital Corporation and LeukoSite, Inc. entered into a License Agreement under which LeukoSite, Inc. was granted an exclusive license to the Act-1 hybridoma cell line for the purpose of making, having made, using and selling antibody derived from the Act-1 hybridoma cell line and antibody conjugates in the field of use. Subject to the terms of the agreement, a sample of the Act-1 hybridoma cell line was provided to LeukoSite, Inc.
  9. Except as set forth in Paragraphs 6-8, samples of the Act-1 hybridoma cell line have not been provided from my laboratory to any others.
  10. Dr. Lazarovits and I remained in contact until his death in January 1999. It is my understanding that Dr. Lazarovits did not distribute the Act-1 hybridoma cell line from his laboratory.
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I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Robert B. Colvin, M.D.11/09/01

Date